PATENT

Attorney Docket No. 16683-1-2

#16
Supp. Declaration
J. Bupa
11/29/01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Examiner: P. Prebilic
GERALD BLATT	Art Unit: 3738
Application No. 09/289,000	SUPPLEMENTAL DECLARATION OF GERALD BLATT PURSUANT TO 37 CFR 1.132
Filed: February 25, 1997	
For: JOINT TREATING METHOD	

Considered
PBP
12/3/01

I, Gerald Blatt, declare as follows:

I am the inventor of the above-captioned patent application.

I am a medical doctor, received my degree from the State University of New York, and have been a practicing orthopedic surgeon since 1969. Amongst others, I specialize in joint replacement and reconstitution.

I am familiar with U.S. patent 5,207,712 over which the claims of my above-captioned patent application were rejected for anticipation or obviousness.

I confirm all statements I made in my earlier Declaration dated April 19, 2001. This includes my previous statement that with the implant of Cohen, there is no possibility that the opposing resected surfaces of the bones can move relative to each other, for the reasons stated in my earlier Declaration.

I further know from my education and well over 30 years of experience as a practicing orthopedic surgeon specializing in surgery of the hand, including joint replacement and reconstruction, that under no circumstances can sliding surfaces be formed by the fibrous tissue that forms between the resected bone ends of Cohen that are spaced apart by ball (4). Physiological sliding surfaces do not and cannot be formed by fibrous tissue alone as it forms

unless the fibrous tissue grows against and is movable relative to a separate surface. Cohen has no such separate surface.

As is described by Cohen (column 2, lines 26-29), the "metatarsal implant of a biodegradable substance [namely ball 4 implanted between the resected bone ends] ... would eventually be replaced by mature fibrous tissue". Cohen further states (column 2, lines 45-47) that "over time, fibrous tissue extends around the implant, and replaces the implant, which is eventually absorbed into the body". This constitutes an unequivocal and correct description of the physiological process that takes place in Cohen, namely the growth of a continuous body of fibrous tissue that extends from the resected end of one of the bones to the resected end of the other bone. The desired end result is a fusion of the joint, which is the antithesis of motion.

I therefore disagree with the following arguments advanced in the Final Rejection of July 12, 2001 and consider them wrong as being contrary to well-established medical knowledge and physiological facts:

- "Next, Applicant argues that no slidable joint movement is possible with the Cohen devices. However, the Examiner respectfully disagrees and maintains that column 4, lines 38-39 explicitly states that the joint can flex after implantation of the implant. The Examiner cannot interpret the language different from what it explicitly states. *For this reason, a slidable movement over the spacer is clearly provided.*" (Final Rejection, page 5, first full paragraph.)

I disagree that in Cohen movement of the spacer is clearly provided. The italicized portion of the quotation is contrary to and ignores medical knowledge and physiological facts.

Further, as I stated in my earlier Declaration, the statement in Cohen that "flexion and extension of the joint should not result in dislocation of the implant" (column 2, lines 38-39) means and can only mean that when the patient flexes or extends the toe as a whole, the resulting forces applied to the implant should not result in its dislocation. In other words, the implant must be capable of withstanding such forces, thereby preventing motion

and enabling a fusion of the bones by growing the above-mentioned continuous body of fibrous tissue between them.

- In response to the assertion that joint fusion is a goal of Cohen, *the Examiner respectfully disagrees and takes the position that the opposite is true*. Column 2, lines 37-44 explain that the gap of 1 mm or more is to prevent "growth of bone" (i.e. bone fusion) between the bone ends. *The Examiner asserts that this gap leads to an articulating joint.* (Final Rejection, page 5, last full paragraph.)

I disagree with the Examiner's position and assertions as set forth in the italicized portions of the quotation. They are unsupported by Cohen, ignore medical knowledge, and are contrary to physiological facts. Further, the formation of an articulating joint is not Cohen's intent and, more importantly, is not possible with the procedures disclosed in the Cohen patent for the reasons stated in this and my earlier Declaration.

- With regard to the argument that sliding motion is prevented by Cohen, the Examiner respectfully disagrees and takes the position that since the joint can flex and extend with the implant in place (see Col. 4, lines 38-39) such that [sic] *sliding on the ball (4) face would inherently occur.* (Final Rejection, page 6, first sentence of subparagraph (5).)

I disagree with the Examiner's position as set forth in the italicized portion of the quotation. It is contrary to medical knowledge and physiological facts.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, having been warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 USC §1001, and may jeopardize the validity of this application or any patent resulting therefrom.

Date: 8/27/01

Gerald Blatt

PATENT

Attorney Docket No. 16683-1-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Considered 03/19/02

Not considered PBP 12/3/01

In re application of:
GERALD BLATT
Application No. 09/289,000
Filed: February 25, 1997
For: JOINT TREATING METHOD

Examiner: P. Prebilic
Art Unit: 3738

DECLARATION OF RONALD W. SMITH PURSUANT TO 37 CFR 1.132

I, Ronald W. Smith, declare as follows:

I am a medical doctor, received my degree from the University of California at San Francisco, California, in 1967, and have been a practicing orthopedic surgeon since about 1975.

Over the last approximately 20 years I exclusively devoted my orthopedic surgeon practice to orthopedic surgery on the foot and ankle.

I am an associate clinical professor at the University of California in Los Angeles (UCLA) and a co-director of the Orthopedic Foot Clinic at Harbor UCLA Medical Center in Torrance, California.

I am a past president of the American Orthopedic Foot and Ankle Society.

I have lectured on hammer toe surgery, have taught residents and fellows surgical treatment of hammer toe surgery, and have had extensive surgical experience in toe surgery in general.

Attached hereto is a copy of my curriculum vitae (17 pages).

I am familiar with Dr. Gerald Blatt's above-captioned patent application (the "Blatt application") and with U.S. patent 5,207,712 (Cohen).

Attached hereto is a copy of A. Shaw et al., *The Use of Digital Implants for the Correction of Hammer Toe Deformity and Their Potential Complications and Management*, 31 The Journal of Foot Surgery 63-74 (January/February 1992), which is referred to in column 1, lines 29-33 of the Cohen patent.

The Blatt application discloses reconstituting damaged non-weight bearing joints, such as finger joints. My orthopedic surgery experience as well as the Cohen patent relate to reconstituting damaged toe joints. It is important to distinguish between the functions of the foot and the toes and the functions of the hand and the fingers. Although both consist of phalanges and associated joints, the predominant function of the foot, weight bearing, requires stability. In contrast, the predominant function of the hand requires dexterity and motion.

The method disclosed in the Blatt application employs an implant that has a convexly curved face which forms a sliding surface and permits sliding motion between the implant and the opposing resected bone and promotes the growth of fibrocartilage.

The Cohen patent teaches the use of an implant between resected ends of opposing bones that has a spacer with stems that extend from the spacer and penetrate into the opposing bones to promote stability and alignment. The Cohen implant is designed to meet the stability requirements of the foot, which differ significantly from the motion requirement for implants implanted in finger joints, for example. Nowhere in the Cohen patent do I find an intent for or capability of a Cohen implant to promote or permit articular motion.

I am familiar with the silicon implant referred to in column 1, lines 16-42 of the Cohen patent. That implant is discussed in greater detail in the attached Journal of Foot Surgery article from 1992. The article correctly describes the functioning of such silicon implants in the first paragraph, right-hand column on page 63, of the article as follows:

> "It is erroneous to assume that the use of the implant will restore joint function following arthroplasty. *The only true function of the implant is to act as a spacer to maintain proper digital length and position, while fibrous tissue matures in the operative site.* In fact, if removal of the implant becomes necessary, the toe will

remain stable so long as the device has been in place at least 6 weeks." (italics added)

I have personally operated on toes having silicon implants. Such implants have a spacer and stems that protrude from each side of the spacer and penetrate the opposing bone ends, which interface at the joint. Such joints, when I operated on them, were stiff and permitted essentially no motion at the joint, although the toe was stable, as desired. I observed that the fibrous tissue mentioned in the Journal of Foot Surgery article surrounds the silicon implant and forms a continuous, fibrous tissue body from one of the opposing bones to the other bone, with the silicon implant typically disposed inside the fibrous tissue.

In fact, the above quotation from page 63 of the 1992 Journal of Foot Surgery states that even if the silicon implant is removed, "the toe will remain stable so long as the device has been in place at least 6 weeks". This is in accord with my own experience and observations in orthopedic foot (toe) surgery, namely that with silicon implants a continuous fibrous tissue body extends uninterrupted from one bone end to the other which stabilizes the toe while it provides effectively no motion at the joint other than some bending of the continuous fibrous tissue body, which can take place when a sufficient force is applied.

I have personally used the ORTHOSORB® absorbable pin referred to in column 1, lines 53-54 of the Cohen patent. These pins differ from the earlier discussed silicon implants in that the former are made of a resorbable material and do not have a spacer. Like the silicon implant, the ORTHOSORB® pins, if implanted at a joint (which is not their intended use), will immobilize the joint and prevent relative motion between the opposing bones.

The Cohen patent teaches to construct the implant of a resorbable material which is absorbed over a period of time. As is described in column 2, lines 45-47 of Cohen, "over time, fibrous tissue forms around the implant, and replaces the implant, which is eventually absorbed into the body". After this has occurred, only fibrous tissue remains between the opposing bone ends of the toe joints in question, which forms a continuous fibrous tissue body as encountered with the above-described silicon implant, except that after resorption no implant remains inside the tissue body. This fibrous tissue provides the desired

stability at the joint but does not provide mobility to the toe joint other than the earlier mentioned bending of the continuous fibrous tissue body between the bone ends when a sufficient force is applied.

I know from my education, over 20 years of experience as a practicing orthopedic foot surgeon, and my work on toe joints having silicon implants, which, though not resorbable, perform the same function as the implants disclosed in the Cohen patent, that no sliding surface is or can be formed by the fibrous tissue that grows between the resected bone ends of Cohen, because implants which have stems that penetrate into the bones do not and cannot develop a functional gap that permits articular motion. This is in marked contrast to the implant without stems developed by Dr. Blatt, which permits articular motion at the joint, resulting in slidable motion between the face of the implant and the opposing bone surface and fibroplast growing thereon.

I have read in the Final Rejection dated July 12, 2001 in the Blatt application that the Examiner has taken the position that "the gap of 1 mm or more .... leads to an articulating joint" (page 5, fifth and fourth lines from the bottom, and page 7, subparagraph (8), of the Final Rejection). I strongly disagree with this observation on the basis of my personal knowledge, experience and observations as set forth above.

The gap referred to in the Final Rejection and the Cohen patent is formed by the central spacer of the implant which is located between the resected bone ends and keeps them spaced apart. This gap does not and cannot lead to an articulating joint.

The "solid" rods of the Cohen patent that project from the central spacer and extend into drilled holes in the opposite bone ends prevent slidable motion between the face of the implant and the opposing surface of the cancellous bone, including any fibrous tissue that may form thereon, thereby also preventing the generation of any surface by the fibrous tissue that can accommodate relative slidable motion. As discussed above, the Cohen implant leads to the formation of a continuous fibrous tissue body that extends from one bone end to the other, opposite bone end.

In contrast to Cohen, the implant used in the method of the Blatt application has a face that is free to slide relative to the opposing, cancellous bone surface, and fibrous tissue

growing thereon, because there is no stem that extends from the implant face into the opposing bone. As described in the Blatt application, this leads to the formation of a fibrocartilage surface that permits painfree slidable motion between the face of the implant and the opposing surface of the bone. This cannot be achieved with the Cohen implant.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, having been warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 USC §1001, and may jeopardize the validity of this application or any patent resulting therefrom.

Date: Nov. 19, 2001

Ronald W. Smith

SP 1270343 v1

CURRICULUM VITAE

Ronald W. Smith, M.D.
Balance Orthopaedic Foot and Ankle Center
2651 Elm Avenue, Suite 205, Long Beach, CA 90806

BIRTHDATE: November 27, 1941.

BIRTHPLACE: Los Angeles, California.

EDUCATION/ SPECIAL TRAINING:
Pomona College, Los Angeles, CA, 1959-1963 (B.A.)
University of California, San Francisco 1963-1967 (M.D.)
Internship: Los Angeles County/Harbor General Hospital Torrance, California, Rotating, 1967-68.
Residency:
General Surgery, Los Angeles County/Harbor General Hospital, 1968-69.
Orthopaedic Surgery, Los Angeles County/Harbor General Hospital, 1969-73. Rancho Los Amigos Hospital, Downey, California, July-December 1970. Orthopaedic Hospital, Los Angeles, July 1971- March 1972.
Fellowship: Giannestras-Schmerge Fellowship for Orthopaedic Surgery of the Foot, September 1975-August 1976.

MILITARY SERVICE
U.S. Navy: Naval Hospital and Marine Corps Recruit SERVICE: Depot, San Diego, California, July 1973-June 1975.

ACADEMIC/ TEACHING APPOINTMENTS:
Instructor, Department of Orthopaedic Surgery, University of Cincinnati, 1975-1976.
Instructor, Department of Surgery, Division of Orthopaedic Surgery, University of California at Los Angeles, 1976-1979.
Assistant Clinical Professor, Division of Orthopaedic Surgery, University of California at Los Angeles, 1979-1988.
Associate Clinical Professor, Division of Orthopaedic Surgery, University of California at Los Angeles, July 1988 to present.
Chief of Foot Service, Harbor-UCLA Medical Center, Torrance, 1979 to present.
Co-Director of Fellowship Program, Balance Orthopaedic/Harbor-UCLA Medical Center Foot and Ankle Fellowship, August 1, 1990, to present.

VISITING PROFESSORSHIP:

Yang Hsueh Chi Visiting Orthopaedic Professorship, University of Hong Kong, June 26-27, 1999.

Ronald W. Smith, M.D.

PROFESSIONAL SOCIETY MEMBERSHIPS:

National: American Orthopaedic Association
American Academy of Orthopaedic Surgeons.
American Orthopaedic Foot and Ankle Society.
American Medical Association.

Regional: Western Orthopaedic Association.
California Medical Association.

Local: Los Angeles County Medical Association.

Appointments in Above Organizations:

American Academy of Orthopaedic Surgeons (AAOS):
Chairman, National Membership Committee, 1992.
Secretary (West), National Membership Committee, 1988-1992.
Member, Committee on the Foot and Ankle, 1984-1990, 1992-1997.
Member, Committee on Educational Programming, 1993-1998.
Member, Program Subcommittee on Foot and Ankle, 1998-2000.
Member, Committee on Ethics, 1993-1994.
Member, Committee on Evaluation, 1989-1991.
Member, Regional Admissions Committee 17, 1985-1988.

American Orthopaedic Foot and Ankle Society (AOFAS):
President, 1998-99.
President-Elect, 1997-98
Vice-President and Treasurer, 1996-97
Treasurer, 1994 to 1997.
Chairman, Arthritis Committee, 1992-1994.
Member, Committee on Diagnostic and Procedural Coding, 1989-1993.
Chairman, Program Committee, Annual Meeting, 1987.
Chairman, Research Committee, 1984.
Associate Editor, FOOT & ANKLE, Journal of the AOFAS,
1986 to present.

Course Directorship:

Co-Chairman, American Academy of Orthopaedic Surgeons Course:
Foot and Ankle—Surgical Techniques, April 28-30, 1988, Washington, D.C.
Co-Chairman, American Academy of Orthopaedic Surgeons 1st Annual
Comprehensive Foot and Ankle Course, November 9-12, 1988, Chicago.
Co-Chairman, American Academy of Orthopaedic Surgeons 2nd Annual
Comprehensive Foot and Ankle Course, November 8-11, 1989, San Francisco.

Ronald W. Smith, M.D.

LICENSURE/CERTIFICATION:

State of California Medical License A 22878, 1967.
American Board of Orthopaedic Surgery, 1974.
Qualified Medical Evaluator, Orthopaedic Surgery, California

HOSPITAL APPOINTMENTS:

Memorial Medical Center of Long Beach:
Member, Board of Directors, 1992-2001
Member, Board of Trustees, Memorial Health Services, 1992-2001
Member, Corporate Audit Committee, 1993-2001.
Chairman, Facilities Planning Committee, 1997-2001
Chairman, Medical Director of Critical Care Search Committee, 1992.
Chairman, Orthopaedic Quality Assurance Committee, 1990-94,1997-2001.
Chairman, Orthopaedic Credentials Committee, 1986-1989.
Member, Memorial Quality Assurance, 1990-1995.
Member, Ortho/Neuro/Rehab Care-Line Committee, 1997-99.
Member, Integrated Quality Improvement Council, 1997.
Member, Memorial Credentials Committee, 1986-89.
Member, Orthopaedic Executive Committee, 1986 to present.

BIBLIOGRAPHY

ARTICLES PUBLISHED:

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Giannestras, N.J., and Smith, R.W. Grice Arthrodesis in Nonparalytic Flexible Flat Feet. In The Foot and Ankle. New York: Brian C. Decker, 1980.

Smith, R.W., and Staple, T.W. CT Scanning for the Hindfoot. In symposium The Hindfoot. Clinical Orthopaedics and Related Research No. 177. Philadelphia and Toronto: J.B. Lippincott, 1983.

Smith, R.W., Reynolds, J.C., and Stewart, M.J. (Research Committee, AOFAS). Hallux Valgus Assessment: Report of Research Committee of American Orthopaedic Foot and Ankle Society. Foot & Ankle 5:2, 1984.

Smith, R.W., and Reischl, S.F. Treatment of Ankle Sprains in Young Athletes. The American Journal of Sports Medicine, 14:465-471, 1986.

Smith, R.W., and Reischl, S.F. Metatarsophalangeal Joint Synovitis in Athletes. In Clinics in Sports Medicine, vol. 7. Philadelphia: W. B. Saunders Company, 1988.

Smith, R.W., and Reischl, S.F. The Influence of Dorsiflexion in the Treatment of Severe Ankle Sprains: An Anatomical Study. Foot & Ankle 9:28-33, 1988.

Brand, J.C., and Smith, R.W.: Rupture of the Flexor Hallucis Longus after Hallux Valgus Surgery: Case Report and Comments on Technique for Adductor Release. Foot & Ankle 11:407-410, 1991.

Smith, R.W., Joanis, T.L., and Maxwell, P.D.: Great Toe Metatarsophalangeal Joint Arthrodesis: A User-Friendly Technique. Foot & Ankle 13:367-377, 1992.

Hayes, W.R., and Smith, R.W.: Forefoot disorders. Current Opinion in Orthopedics 4(3):8-12, 1993.

Conklin, M.J., and Smith, R.W.: Treatment of the Atypical Lesser Toe Deformity with Basal Hemiphalangectomy. Foot & Ankle 15:585- 594, 1994.

Lehman, D.E., and Smith, R.W.: Treatment of Symptomatic Hammertoe with a Proximal Interphalangeal Joint Arthrodesis. Foot & Ankle 16(9):535-541, 1995.

Hayes, W.R., and Smith, R.W.: Trochanteric Bone Grafts in Foot and Ankle Surgery. Foot & Ankle International, 17(7):402-405, July 1996.

Sima, W.F., Smith, R.W., Reischl, S., and Ebramzadeh, E.: Hallux Rigidus Treated by Chellectomy: Factors Influencing Outcome. Submitted for publication, Foot & Ankle International, July 1998.

Thomas, P.J., and Smith, R.W.: Proximal Phalanx Osteotomy for the Surgical Treatment of Hallux Rigidus. Foot & Ankle International, 20(1):3-12, January 1999.

Caronis, G.G., and Smith, R.W.: Forefoot Disorders. Current Opinion in Orthopedics, 10(3):231-235, June 1999.

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Smith, R.W., Katchis, S.D., and Ayson, L.C.: Outcomes in Hallux Rigidus Patients Treated Nonoperatively: A Long-Term Follow-Up Study. Foot & Ankle International, 21(11):906-913, November 2000.

BOOK CHAPTERS PUBLISHED:

Smith, R.W. Ancillary Studies: Computed Tomographic Scans. In Gould, J.S. (ed): The Foot Book. Baltimore: Williams & Wilkins, 1988.

Smith, R.W. Calluses: Nonsurgical Treatment. In Gould, J.S. (ed): The Foot Book. Baltimore: Williams & Wilkins, 1988.

Smith, R.W. Computerized Sectional Imaging: Computed Tomography and Magnetic Resonance Imaging of the Foot and Ankle. In Jahss, M.H. (ed): Disorders of the Foot and Ankle. Medical and Surgical Management, 2nd ed., Vol. 1. Philadelphia: W.B. Saunders, 1991, pp. 155-204.

Smith, R.W. Ankle Arthrodesis. In The Foot and Ankle, Johnson, K. A. (ed of Vol), Master Techniques in Orthopaedic Surgery, Thompson, Jr., R.C. (Series Ed). New York: Raven Press, 1994, pp. 467-482.

GUEST EDITOR:

Smith, R.W., and Wagner, F.W., guest eds. Symposium Disorders of the Forefoot Clinical Orthopaedics and Related Research No. 142. Philadelphia and Toronto: J.B. Lippincott, 1979.

SCIENTIFIC EXHIBITS:

"CT Scan Evaluation of the Hindfoot–An Anatomical and Clinical Study." Scientific Exhibit with Tom W. Staple, M.D., at annual meeting of AAOS, Anaheim, California, March 1983.

PRESENTATIONS AT PROFESSIONAL SOCIETY MEETINGS:

"Cysts of the Os Calcis." Presented at annual meeting of Los Angeles Chapter, Western Orthopaedic Association, Indian Wells, California, March 1973.

"Ankle and Foot Injuries." Presented at annual meeting of Ohio Chapter, American College of Surgeons, Cincinnati, Ohio, May 1976.

"The Grice Arthrodesis in Flexible, Nonparalytic Flat Feet." Presented at annual meeting of American Orthopaedic Foot Society, Dallas, Texas, February 1978.

"Vascular Occlusive Disease of the Foot and Its Care." Presented at American College of Surgeons orthopaedic symposium, San Francisco, California, October 1978.

"Melanoma of the Foot." Presented at annual meeting of American Orthopaedic Foot Society, Atlanta, Georgia, February 1980.

"Diabetic Ulcers—Etiology: Neuropathy or Ischemia?" Co-author with Anthony Richards, M.D., Barbara Schmitz, R.N., and Kevin Tremper, M.D. Paper presented at annual meeting of American Orthopaedic Foot Society, Atlanta, Georgia, February 1980.

"Calcaneal Plantar Fasciitis--A Study of Nonoperative Treatment." Presented at annual meeting of American Orthopaedic Foot Society, Las Vegas, Nevada, February 1981.

"CAT Scan Evaluation of the Hindfoot--An Anatomical and Clinical Study." Co-author with Tom W. Staple, M.D. Paper presented at annual meeting of American Orthopaedic Foot Society, New Orleans, Louisiana, January 1982.

"Chronic Problems of the Adult Foot." Presented at Annual Scientific Assembly, California Medical Association, Anaheim, California, March 1982.

"Heel Pain." Presented as Instructional Course at annual meeting of American Academy of Orthopaedic Surgeons (AAOS), Anaheim, California, March 1983.

"Influence of Ankle Dorsiflexion in the Treatment of Severe Ankle Sprains." Presented at meeting of Los Angeles Chapter, Western Orthopaedic Association, May 1985.

"Ankle Block Anesthesia and Other Practical Techniques for Outpatient Surgery." Presented at symposium, AAOS annual meeting, New Orleans, Louisiana, February 1986.

"Influence of Dorsiflexion on Treatment of Severe Ankle Sprains: An Anatomical Study." Co-author with S.F. Reischl and L. Ficke. Presented at AAOS annual meeting, New Orleans, Louisiana, February 1986.

"Fracture Morphology as Seen with CT Scanning." Presented at symposium on surgical management of acute calcaneal fractures, Annual Meeting of American Orthopaedic Foot and Ankle Society, San Francisco, January 22, 1987.

"Great Toe Metatarsophalangeal Joint Arthrodesis: A 'User- Friendly' Technique." Presented at annual summer meeting, American Orthopaedic Foot and Ankle Society, Sun Valley, Idaho, August 6, 1989.

"Midfoot-Hindfoot Image Anatomy, CT, MRI." Presented at annual summer meeting, American Orthopaedic Foot and Ankle Society, Sun Valley, Idaho, August 6, 1989.

"Great Toe Metatarsophalangeal Joint Arthrodesis: A 'User-Friendly" Technique." Presented at annual meeting of Western Orthopaedic Association, Anaheim, California, October 26, 1989.

"Hallux Valgus Correction with Proximal Metatarsal Osteotomy." Presented at symposium on contemporary decisions in forefoot surgery, AAOS annual meeting, New Orleans, Louisiana, February 9, 1990.

"Newer Radiographic Evaluation of Calcaneal Fractures." Presented at symposium, annual meeting of American Orthopaedic Foot and Ankle Society, New Orleans, February 11, 1990.

"Hallux Rigidus Treated with Cheilectomy." Co-Author with William F. Sima, M.D., and Stephen F. Reischl., P.T. Presented by Dr. Sima at Annual Meeting of American Orthopaedic Foot and Ankle Society, Washington, D.C., February 23, 1992, and Annual Meeting of Western Orthopaedic Association, Tucson, Arizona, October 23, 1991.

"Bunions and Hammertoes." Presented at Annual Meeting of California Orthopaedic Association, Rancho Mirage, CA, May 3, 1992.

"Results of Lesser Toe Basal Hemiphalangectomy." Co-Author with Mark J. Conklin, M.D. Presented by Dr. Conklin at Western Orthopaedic Association meeting, Monterey, CA, October 13, 1992.

"Torsional Problems of the Lower Extremity," and "Heel Pain." Presented at American Academy of Family Physicians National Assembly, San Diego, CA, October 18, 1992.

"Heel Pain." Presented at California Medical Association Western Scientific Assembly: Update on the Foot and Ankle, Anaheim, CA, February 27, 1993.

"Salvage of the Atypical Lesser Toe Deformity With a Basal Hemiphalangectomy." Co-Author with Mark J. Conklin, M.D. Presented by Dr. Conklin at 23rd Annual Meeting of American Orthopaedic Foot and Ankle Society, San Francisco, CA, February 21, 1993.

"Can We Meaningfully Measure the Flat Foot? A Multi-Examiner Comparison of Radiographic Arch Structure Measurements. Co- Author with William F. Sima, M.D., and Stephen Reischl, P.T., O.C.S. Presented by Dr. Smith at 1993 Summer Meeting, American Orthopaedic Foot and Ankle Society, Asheville, N.C., July 24, 1993.

"Proximal Interphalangeal Joint Arthrodesis." Presented at surgical techniques session, 1993 Summer Meeting, American Orthopaedic Foot and Ankle Society, Asheville, N.C., July 25, 1993.

"Torsional Problems of the Lower Extremity" (Child's Foot and Ankle Section). Presented at American Academy of Family Physicians Assembly, Orlando, Florida, October 6, 1993.

"Heel Pain." Presented at American Academy of Family Physicians Assembly, Orlando, Florida, October 6, 1993.

"Tendon Injuries." Presented at Bi-Annual Scientific Meeting of Western Slope Chapter, Western Orthopaedic Association, Aspen, Colorado, October 22-23, 1993.

"Atypical Sprains--Syndesmotic and Deltoid Ligament Injuries." Instructional Course Lecture presented at Annual Meeting of American Academy of Orthopaedic Surgeons, February 17, 1995, Orlando, Florida.

"Management of the Acute Ankle Sprain and the Influence of Dorsiflexion in Its Care." Instructional Course Lecture presented at Annual Meeting of American Academy of Orthopaedic Surgeons, February 17, 1995, Orlando, Florida.

"Outcomes in Hallux Rigidus Treated Non-Operatively: A Ten Year Follow-up Study." Co-Author with S. Katchis and L. Ficke. Presented by Dr. Smith at First Combined Meeting of the American, British and European Foot and Ankle Surgeons, August 25, 1995, Dublin, Ireland.

Presentations at the Latin American Congress of Orthopaedics and Traumatology and Colombian Congress of Orthopaedics and Traumatology, October 1-11, 1995, Bogota, Colombia:
"Ankle Ligament Lesions in the Athlete."
"Tendon Injuries: "Other Tendons."
"Ankle Intra-Articular Fractures."
"Ankle Arthrodesis: Indications, Techniques, and Results."
"Heel Pain"

"Atypical Sprains--Syndesmotic Injuries." Presented at Instructional Course, American Academy of Orthopaedic Surgeons Annual Meeting, February 26, 1996, Atlanta Georgia.

"Management of the Acute Ankle Sprain and the Influence of Dorsiflexion in its Care." Presented at Instructional Course, American Academy of Orthopaedic Surgeons Annual Meeting, February 26, 1996, Atlanta, Georgia.

"Outcomes in Hallux Rigidus Patients Treated Nonoperatively: A Ten- Year Follow-up Study." Presented at the American Orthopaedic Foot and Ankle Society 12th Annual Summer Meeting, June 30, 1996, Hilton Head, South Carolina.

"Management of the Acute Ankle Sprain and the Influence of Dorsiflexion in its Care." Presented at Instructional Course, American Academy of Orthopaedic Surgeons Annual Meeting, February 15, 1997, San Francisco, CA.

"Atypical Sprains--Syndesmotic Injuries." Presented at Instructional Course, American Academy of Orthopaedic Surgeons Annual Meeting, February 15, 1997, San Francisco, CA.

"Cheilectomy with Proximal Phalanx Osteotomy for Surgical Treatment of Hallux Rigidus." Co-Author with Patrick J. Thomas, M.D.. Presented by Dr. Thomas at Annual Meeting of American Orthopaedic Foot and Ankle Society, February 16, 1997, San Francisco.

"Management of Severe Acute Ankle Sprains," as part of Symposium on Foot and Ankle Injuries in the Elite Athlete. Presented at Annual Summer Meeting of American Orthopaedic Foot and Ankle Society, July 17, 1997, Monterey, California.

Symposium "Management of the Flat Foot in Young and Old," Presenter and moderator. Annual Summer Meeting of American Orthopaedic Foot and Ankle Society, July 17, 1997, Monterey, California.

"Is It a Flatfoot or a Hyperpronated Foot?" Presented at annual meeting of Puerto Rico Orthopaedic Surgery Association, August 30, 1997, Dorado, Puerto Rico.

"Hallux Rigidus -- A Perspective." Presented at annual meeting of Puerto Rico Orthopaedic Surgery Association, August 31, 1997, Dorado, Puerto Rico.

"Proximal Phalanx Osteotomy for the Surgical Treatment of Hallux Rigidus." Co-author with Patrick J. Thomas, M.D. Presented by Dr. Smith at Combined Meeting of the American Orthopaedic Foot and Ankle Society and the Japanese Society for Surgery of the Foot, November 15, 1997, at Walkoloa, Hawaii.

"Management of the Acute Ankle Sprain and the Influence of Dorsiflexion in its Care." Presented at Instructional Course, American Academy of Orthopaedic Surgeons Annual Meeting, March 23, 1998, New Orleans, LA.

"Atypical Sprains--Syndesmotic Injuries." Presented at Instructional Course, American Academy of Orthopaedic Surgeons Annual Meeting, March 23, 1998, New Orleans, LA.

"Peroneus Longus Tendinopathy." Co-author with Clayton Brandes, M.D. Presented by Dr. Smith at 2nd Combined Meeting of Foot and Ankle Surgeons (CoMFAS), September 19, 1998, Venice, Italy.

"Concepts of Management in Posterior Tibial Tendon Dysfunction." Presented at meeting of Western Orthopaedic Association, Orange County Chapter, November 18, 1998, Orange, CA.

"Rupture of the Posterior Tibial Tendon: Don't Discard the Tendon," Presented at meeting of French Society of Medicine and Surgery of the Foot," December 12, 1998, Paris.

"Natural History and Nonoperative Modalities," in Symposium: New Perspectives In Hallux Rigidus. Presented at 29th Annual Meeting of American Orthopaedic Foot and Ankle Society, February 7, 1999, Anaheim, California.

"Peroneus Longus Injuries: Characteristics, Diagnosis, and Treatment." "Hallux Rigidus: A Perspective." Guest Speaker presentations at 10th Annual Southeastern Orthopaedic Foot Club Meeting, April 29, 1999, Point Clear, Alabama.

"An Anatomical Approach to the Treatment of Acute Ankle Sprains." Presented at Alabama Orthopaedic Society Meeting, April 30, 1999, Point Clear, Alabama.

"The Foot in Diabetes Mellitus." 3rd Annual Yang Hsueh Chi Lecture, Hong Kong University, June 29, 1999. Faculty in Hong Kong Orthopaedic Association Foot and ankle Symposium, June 26-27, 1999.

"Surgical Treatment of Peroneus Longus Injuries." Presented as part of Symposium, Congress of the International Federation of Foot and Ankle Societies IFFAS, Kyoto, Japan, October 13-16, 1999.

Presentations at Brazil Foot and Ankle Society's Annual Symposium, December 10-11, 1999, Sao Paulo, Brazil:
"The Diabetic Charcot Foot: Principles of Management";
"Heel Pain: Can We Make the Management Simple?";
"Common and No-So-Common Sports Injuries of the Foot and Ankle";
"The Rheumatoid Foot: How Can We Improve Our Management?"
"Posterior Tibial Tendon Dysfunction: Current Concepts of Management";
"Forefoot Surgery: Lessons from the Complications."

Moderator, "Managing Foot Care in Offices and Clinics, Instructional Course presented at annual meeting of American Academy of Orthopaedic Surgeons, Orlando, Florida, March 16, 2000.

"Operating Room Efficiencies in Foot Surgery." Presented at Instructional Course, annual meeting of American Academy of Orthopaedic Surgeons, Orlando, Florida, March 16, 2000.

Ronald W. Smith, M.D.

COURSE PRESENTATIONS/LECTURES:

"Pes Planus." Presented as part of American Academy of Orthopaedic Surgeons (AAOS) course "The Lower Extremity in the Growing Child," Los Angeles, California, April 1979.

"Evaluation of Flatfoot Deformity by CAT Scan." Presented at AAOS Continuing Education Course on Practical Treatment of the Foot and Ankle for Practicing Orthopaedic Surgeons, New Orleans, Louisiana, April 23, 1983.

"Practical Management of the Rheumatoid Foot." Presented at AAOS course in New Orleans, Louisiana, April 23, 1983.

"The Operative Treatment of Difficult Nail Pathology." Presented at AAOS Course on the Foot and Ankle—Trauma, Sports, and Reconstructive Procedures, Santa Monica, California, November 28, 1983.

"Heel Pain—Evaluation and Nonoperative Treatment." Presented at AAOS course in Santa Monica, California, November 28, 1983.

"Tarsal Coalitions—CAT Scanning, Diagnosis and Treatment." Presented at AAOS course in Santa Monica, California, November 28, 1983.

"Soft Tissue Injuries, Ligament Sprains, Ruptures, Diagnoses, and Treatment (Closed vs. Open)." Presented at AAOS course in Santa Monica, California, November 30, 1983.

"Nail Pathology—Office Care and Operative Treatment." Presented at AAOS and AOFAS Course on Adult Foot and Ankle Problems Related to Reconstructive Procedures, Trauma and Sports Medicine, San Francisco, California, November 12, 1984.

"Radiologic Evaluation of the Foot and Ankle: Special Studies." Presented at AAOS and AOFAS course in San Francisco, California, November 12, 1984.

"Tarsal Coalitions: Diagnosis and Treatment." Presented at AAOS and AOFAS course in San Francisco, California, November 12, 1984.

"Sepsis of Foot and Foreign Bodies." Presented at AAOS and AOFAS course in San Francisco, California, November 13, 1984.

"Nail Care." Cadaver TV Surgical Demonstration, AAOS and AOFAS course in San Francisco, California, November 13, 1984.

"Ankle Problems--Ligaments." Presented at AAOS and AOFAS course in San Francisco, California, November 14, 1984.

"Toe Pathology--Operative Treatment." Presented at AAOS and AOFAS course in Scottsdale, Arizona, May 24, 1985.

"Nail Pathology--Operative Treatment." Presented at AAOS and AOFAS course in Scottsdale, Arizona, May 24, 1985.

"Special Diagnostic Techniques for Evaluating the Midfoot and Hindfoot." Presented at AAOS and AOFAS course in Scottsdale, Arizona, May 25, 1985.

"Tarsal Coalitions." Presented at AAOS and AOFAS course in Scottsdale, Arizona, May 25, 1985.

"Foot and Ankle--Trauma and Reconstructive Procedures." Member of Faculty at American Academy of Orthopaedic Surgeons course in Houston, Texas, October 1985.

"CT Scan Evaluation of the Foot." Presented at symposium on the foot, Colombia Orthopaedic Society, Bogota, Colombia, March 1986.

"Fractures of the Foot." Presented at symposium on the foot, Colombia Orthopaedic Society, Bogota, Colombia, March 1986.

"The Foot in Diabetes Mellitus." Presented at symposium on the foot, Colombia Orthopaedic Society, Bogota, Colombia, March 1986.

"The Foot in Rheumatoid Arthritis." Presented at symposium on the foot, Colombia Orthopaedic Society, Bogota, Colombia, March 1986.

"Surgical Management of Ingrown Toenails." Presented at AAOS continuing education course in Cleveland, Ohio, April 21, 1986.

"Morton's Neuroma." Presented at AAOS continuing education course in Cleveland, Ohio, April 21, 1986.

"Value of CT Scan in the Diagnosis of Foot Disorders." Presented at AAOS continuing education course in Cleveland, Ohio, April 22, 1986.

"Diagnosis and Treatment of Ankle Sprains." Presented at AAOS continuing education course in Cleveland, Ohio, April 23, 1986.

"Patient Evaluation: Radiographic Techniques, Scans, MRI." Presented at AAOS Summer Institute, Monterey, California, September 22, 1986.

"Hard Corns and Soft Corns, Hammertoes and Clawtoes: Treatment." Presented at AAOS Summer Institute, Monterey, California, September 23, 1986.

"Pathology Involving Lisfranc's Joints." Presented at AAOS Summer Institute, Monterey, California, September 24, 1986.

"Tendon Pathology of the Foot--Selected Problems." Presented at AAOS Summer Institute, Monterey, California, September 24, 1986.

"Complications and Salvage Procedures for Hallux Valgus." Presented at AAOS course, Los Angeles, CA, November 15, 1986.

"Metatarsalgia and Interdigital Neuroma." Presented at AAOS course, Los Angeles, California, November 15, 1986.

"Ankle Sprains: How We Treat Them and Why." Presented at AAOS course, Los Angeles, California, November 15, 1986.

"Reconstruction for Complications of Os Calcis Fractures." Presented at AAOS course, Orlando, Florida, March 11, 1987.

"Shoes and Orthoses for Insensitive Feet." Presented at AAOS course, Orlando, Florida, March 13, 1987.

"Toenail Problems." Presented at AAOS course, Orlando, Florida, March 14, 1987.

"Patient Evaluation: Electrodiagnostic Tests." Presented at AAOS course The Adult Foot and Ankle--Diagnostic and Treatment Concepts, San Diego, California, November 5-7, 1987.

"Toe Nail Procedures." Presented at AAOS course, San Diego, California, November 5-7, 1987.

"Arthrodesis of the Hallux Interphalangeal Joint with AO Screw Fixation--Technique." Presented at AAOS course, San Diego, California, November 5-7, 1987.

"Hammertoe Correction with Middle Joint Arthrodesis and Capsulotomy of the Metatarsophalangeal Joint--Technique." Presented at AAOS course, San Diego, California, November 5-7, 1987.

"The Flexible Flatfoot: Evaluation and Treatment." Presented at AAOS course, San Diego, California, November 5-7, 1987.

"Tarsal Coalitions: Diagnosis, Excision Versus Arthrodesis." Presented at AAOS course, San Diego, California, November 5-7, 1987.

"CT and MRI." Presented at AAOS course Foot and Ankle—Surgical Techniques, Washington, D.C., April 28, 1988.

"Hallux Valgus Correction with Arthrodesis." Presented at AAOS course Foot and Ankle—Surgical Techniques, Washington, D.C., April 28, 1988.

"Management of the Acute Ankle Sprain." Presented at AAOS course Foot and Ankle—Surgical Techniques, Washington, D.C., April 29, 1988; First Annual Comprehensive Foot and Ankle Course, AAOS, Chicago, Illinois, November 9-12, 1988; and Second Annual Comprehensive Foot and Ankle Course, AAOS, San Francisco, California, November 9, 1989.

"Diagnosis and Treatment of Lisfranc Dislocations." Presented at AAOS Summer Institute, San Diego, California, September 10, 1988.

"Hallux Valgus Correction with MP Arthrodesis." Surgical Demonstration, First Annual Comprehensive Foot and Ankle Course, AAOS, Chicago, Illinois, November 12, 1988, and Second Annual Comprehensive Foot and Ankle Course, AAOS, San Francisco, California, November 11, 1989.

"Other tendon Injuries of the Foot and Ankle." Presented at Second Annual Comprehensive Foot and Ankle Course, AAOS, San Francisco, California, November 9, 1989.

"Metatarsophalangeal Arthrodesis: A Basic Technique & Results." Presented at Third Annual Comprehensive Foot and Ankle Course, AAOS, Chicago, Illinois, November 7, 1990; Fourth Annual Comprehensive Foot and Ankle Course, San Francisco, November 16, 1991.

"Tarsal Coalition." Presented at Third Annual Comprehensive Foot and Ankle Course, AAOS, Chicago, Illinois, November 10, 1990; Fourth Annual Comprehensive Foot and Ankle Course, San Francisco, November 16, 1991.

"Management of the Acute Ankle Sprain." Presented at Third Annual Comprehensive Foot and Ankle Course, AAOS, Chicago, Illinois, November 10, 1990; Fourth Annual Comprehensive Foot and Ankle Course, San Francisco, November 16, 1991.

"Can We Meaningfully Measure the Flatfoot? Analysis of Radiographs and Footprints." resented as part of the 14th Annual Continuing Orthopaedic Education Program of the Harbor- UCLA Medical Center Orthopaedic Alumni, at Long Beach Memorial Center for Health Education, May 24, 1991.

"Morton's Neuroma," "Heel Pain," "The Foot in Diabetes Mellitus." Lecture for Family Practice Physicians, La Palma Intercommunity Hospital, La Palma, California, October 17, 1991.

"Ankle Sprains and Peroneal Tendon Problems." "Tendon Injuries." Orthopaedic Resident Review Course, San Francisco, California, October 20, 1991.

"Take a Stand: Ethics Issues." Orthopaedic Grand Rounds presentation, Harbor-UCLA Medical Center, Torrance, California, February 11, 1992.

"Imaging for Injuries of the Foot and Ankle." Orthopaedic Grand Rounds presentation, Harbor-UCLA Medical Center, Torrance, California, March 18, 1992.

"Imaging for Injuries of the Foot and Ankle," "Midfoot Fusion," "Ankle Ligament Injuries." Presented at AAOS course, Foot and Ankle – Advanced Surgical Strategies, Rancho Mirage, California, March 25-28, 1992.

"Common Foot & Gait Deformities in the Child." Presented at Pediatric Grand Rounds," Long Beach Memorial Medical Center, May 8, 1992.

"Hallux Rigidus Treated by Cheilectomy." Presented at Annual Continuing Orthopaedic Education Program of Harbor-UCLA Medical Center, Long Beach, CA, May 22, 1992.

"The Diabetic Foot." Presented at Surgery Grand Rounds, Harbor- UCLA Medical Center, Torrance, CA, September 19, 1992.

"Jones Transfer, IP Arthrodesis." Demonstration at surgical skills course, AAOS Summer Institute, Seattle, WA, September 23, 1992.

"Metatarsophalangeal Arthrodesis: A Basic Technique and Results." "Tarsal Coalition." Presented at AAOS Fifth Annual Comprehensive Foot & Ankle Course, Chicago, October 28/31, 1992.

"Current Concepts in Bunion Surgery." Presented to Seminars in Surgery: Nursing Conference, Long Beach Memorial Medical Center, March 10, 1993.

"Hallux Valgus: Current Concepts." Presented at 3rd Annual Campbell Clinic Symposium, Scottsdale, Arizona, January 27, 1994.

"Acute and Chronic Ankle Sprains: Not a 'Simple' Injury–Current Treatment Recommendations." Presented at 3rd Annual Campbell Clinic Symposium, Scottsdale, Arizona, January 27, 1994.

"Hallux Rigidus - A Perspective." Presented at Orthopaedic Grand Rounds, University of Southern California, Department of Orthopaedics, Los Angeles, March 3, 1994.

"Acute and Chronic Ankle Sprains–Current Treatment Recommendations." Presented at Orthopaedic Grand Rounds, Harbor- UCLA Medical Center, Torrance, March 30, 1994.

"Until They Hurt, We Take Them for Granted." Presented at 20th Annual Review Course, Common Problems in Primary Care, University of Southern California, April 19, 1994.

"Jones Fracture/Metatarsal Fractures." Presented at American Academy of Orthopaedic Surgeons Summer Institute, Intensive Surgical Skills, Monterey, California, September 12, 1994.

"Lesser Toe Deformities." Presented at American Orthopaedic Foot and Ankle Society Review Course, Orthopaedic Hospital, Los Angeles, October 29, 1994.

"Diagnostic and Treatment Dilemmas in the Management of Retrocalcaneal Pain." Presented at 1995 Annual Orthopedic Symposium, Kaiser Permanente, Huntington Beach, California, January 14, 1995.

Presentations at American Academy of Orthopaedic Surgeons course, The Advanced Foot and Ankle Course: Reconstruction and Salvage of Complications, March 30-April 2, 1995, Phoenix, Arizona.
"Failed MTP Fusion"
"Failed Cheilectomy (Why it didn't work, when it doesn't work, what do you do?)
"Management of the Acute Ankle Sprain and the Influence of Dorsiflexion in its Care"

Presentations at American Academy of Orthopaedic Surgeons course, The Advanced Foot and Ankle Course: Reconstruction and Salvage of Complications, March 30-April 2, 1995, Phoenix, Arizona.
"Hindfoot Fusion for Severe Pes Planus"
"Symptomatic Flatfoot: Who Becomes Symptomatic, Who Does Not, Conservative Treatment, Indications for Surgery" (Keynote Address)
"Atypical Sprains--Syndesmotic and Deltoid Ligament Injuries"
"Tarsal Coalition"

"Non-Surgical Care of Hallux Rigidus: A Study of Ten Year Follow- ups." Presented at 18th Annual Continuing Orthopaedic Education Program of Harbor-UCLA Medical Center, June 2, 1995.

Presentations at AAOS 8th Annual Comprehensive Foot and Ankle Course, November 1-4, 1995, San Francisco, CA.
"Chevron Procedure: Basic Technique and Results."
"Hammertoes: Fixed and Flexible."
"Hammertoe Correction: Mild to Severe Deformities Including Cross-Over, Surgical Demonstration."

"Achilles Tendon Repair and Reconstruction." Presentation at AAOS Surgical Skills Course, Orthopaedic Learning Center, Chicago, IL, May 17, 1996.

"Failed MTP Fusion." Presented at Advanced Foot & Ankle Course, Reconstruction and Salvage of Complications, American Orthopaedic Foot & Ankle Society, May 16, 1997, San Francisco, CA.

"Failed Cheilectomy (Why it didn't work, when it doesn't work, what do you do?)." Presented at Advanced Foot & Ankle Course, Reconstruction and Salvage of Complications, American Orthopaedic Foot & Ankle Society, May 16, 1997, San Francisco, CA.

Flat Foot Symposium, Moderator and Presenter of Keynote Address and "Hindfoot Fusion for Severe Pes Planus." Advanced Foot & Ankle Course, Reconstruction and Salvage of Complications, American Orthopaedic Foot & Ankle Society, May 16, 1997, San Francisco, CA.

"Tendon Disorders of the Foot and Ankle." Presented at American Orthopaedic Foot and Ankle Society Regional Review Course: Treatment of the Foot and Ankle," October 4, 1997, Los Angeles.

"Arthritis of the Forefoot." Presented at American Orthopaedic Foot and Ankle Society Regional Review Course: Treatment of the Foot and Ankle," October 4, 1997, Los Angeles,

"Common Problems in the Foot and Ankle." Presented at 24th Annual Review Course, USC Department of Family Medicine, April 7, 1998, Los Angeles, CA.

"Hallux Rigidus – A Perspective." Presented at 21st Annual Continuing Orthopaedic Education Program of Harbor-UCLA Medical Center Orthopaedic Alumni, May 29, 1998.

"Hallux Rigidus." "Acute Ligamentous Injuries of the Ankle." "Injuries of the Peroneus Longus Tendon." Presented at foot and ankle instructional course of the Mexican Orthopaedic Society, Acapulco, Mexico, May 1, 1999.

"Surgery for Subluxated 2nd MTP: Video & Case Presentations." Presented with Michael J. Coughlin, M.D., at AOFAS Advanced Foot and Ankle Course, May 8, 1999, Washington, D.C.

"Problems of the Great Toe." Presented at instructional course Updates in Foot and Ankle Care – What Orthopaedic Surgeons Need to Know, Annual Meeting of California Orthopaedic Association/Northern California Chapter of Western Orthopaedic Association, Monterey, California, May 20, 1999.

"Defining the Flatfoot: Dynamic and Structural Abnormalities." Guest lecture at Nara Medical University, Nara, JAPAN, October 12, 1999.

The Use of Digital Implants for the Correction of Hammer Toe Deformity and Their Potential Complications and Management

This manuscript deals with use of silicone implants as part of the correction for hammer toe deformity. A brief description of the historical correction of hammer toe is presented, with emphasis placed on the development and use of silicone prostheses. The surgical procedure is discussed and an overview of the authors' long-term results are included. Analysis of an informal survey taken of several practitioners known to utilize digital implants is also presented. This manuscript primarily focuses on potential complications that may accompany the procedure. Management and prevention of these complications is also discussed.

Alan H. Shaw, DPM, MS, FACFS[1]
Gregory Alvarez, DPM[2]

The literature is replete with numerous descriptions for the successful treatment of painful hyperkeratotic lesions over the proximal interphalangeal joint of the toe, through the traditional arthroplastic technique (resection of the head of the proximal phalanx) (1–4). Frequently encountered complications with this procedure include the flail, unstable toe, that may also be reduced in length. This has been especially true with the fifth digit. Two alternatives to traditional arthroplastic surgery are the use of Kirschner wire fixation through the operative site for a short period of time (3), or fusion of the proximal interphalangeal joint (5–7). The Kirschner-wire approach can be fraught with complications such as infection and/or displacement because of its external position. Fusion can be technically difficult, the postoperative course is quite prolonged (8 to 12 weeks), and positional results are frequently unpredictable.

After considering the above factors, the use of a silicone implant with digital arthroplasty appears to be an excellent alternative. There is no need for any type of fixation device, and the postoperative course is much shorter than with fusion. The complications with implant arthroplasty are far less than with the two alternative techniques mentioned above, and the results are more predictable (8, 9).

It is erroneous to assume that the use of the implant will restore joint function following arthroplasty. The only true function of the implant is to act as a spacer to maintain proper digital length and position, while fibrous tissue matures in the operative site. In fact, if removal of the implant becomes necessary, the toe will remain stable so long as the device has been in place at least 6 weeks (10).

Historical Perspective

Digital surgery was discussed in the medical literature as early as 1816 (11), and also in 1882 (12). During the early 1900s, many authors began to describe the deformity and proposed a multitude of surgical approaches to remedy it (13–17). Sorto (1) reported a 5-year retrospective study at Northlake Hospital that demonstrated a 90% success rate, with several qualifying points that pertained to digital elevation in relation to the supporting surface, and lack of sagittal and transverse stability of the operated toe. These two factors significantly lowered the overall success rate to 65%.

The use of a silicone prosthetic implant for extremity surgery was pioneered by Swanson (18–27). Implant have been designed and refined by Weil[3] and Sgarlato[4] (8) and Sgarlato and Carine (9) for specific use in the

[1] Diplomate, American Board of Podiatric Surgery. Address correspondence to: 2520 Windy Hill Road, #104, Marietta, Georgia 30067.
[2] Submitted while second year resident, Veteran Hospital, Atlanta.
0449/2544/92/3101-0063$03.00/0

[3] Weil, L. S. SILASTIC® Brand Hammertoe Implant (Swanson Type, Weil Design). Data Sheet: L083-0222. Dow Corning Wright. Arlington, Tenn.
[4] Sgarlato, T. E. The Sawer Lesser toe Proximal Interphalangeal Joint Prosthesis (Sgarlato design): Product literature Sut 45V85. Sutter Biomedical Inc., San Diego, CA.

toes. The basic purpose of these implants is described as being a method to achieve stability of the operated digit, while maintaining the length of the toe.

Implant Product Selection

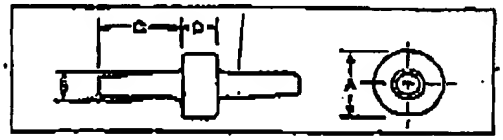
Currently, there exist three products for digital prosthetic implantation available for the foot. All of these devices are composed of medical grade silicone elastomer, one of which is reinforced with a polyester fabric. These will be discussed in the chronological order of their development. The original presentation of pedal digital implantation described use of a Dow Corning SILASTIC® finger joint prosthesis (Swanson Design), but this was fraught with a number of complications (28). With the availability of implants specifically designed for toes, the authors do not recommend use of finger joint prostheses.

SILASTIC® H. P. 100, (Swanson Type) Weil Design, Dow Corning Wright

This is a double-stemmed flexible implant with a cylindrical center body. The implant was introduced in 1976, and a new design was developed in 1987. In the senior author's practice, and the experience of several respondents to an informal questionnaire on digital implants, this particular device is not being utilized as frequently as others. The primary reason is a relatively large diameter of the central portion which, in its smallest model, is 0.25 inches. This characteristic may predispose to a greater likelihood of lesion recurrence and digital swelling (Fig. 1).

Sutter Lesser Toe Proximal Interphalangeal Joint Prosthesis (Sgarlato Design), Sutter Biomedical

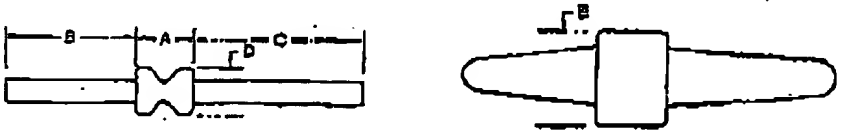
This is a double-stemmed, very flexible implant with a central hinge and rectangular shaped stems, with a polyester mesh internal fabric for reinforcement. The prosthesis was approved for use in 1981, and is widely used today. The central portion of the smallest version of the implant is 0.138 inches, which is significantly smaller than the Dow Corning model described previously. These authors and survey respondents believe the Sutter implant to be the device of choice, primarily because of its reduced size and resultant higher success rate. The ability to insert this implant in various positions (flat, angled, or vertical) also contributes greatly to its efficacy (Figs. 2, 3).



TYPICAL DIMENSIONS

SIZE	A	B	C	D
1S	.25 (6.4)	.10 (2.5)	.36 (9.1)	.079 (2.0)
1	.25 (6.4)	.10 (2.5)	.36 (9.1)	.13 (3.3)
1L	.25 (6.4)	.10 (2.5)	.39 (9.4)	.19 (4.8)
1W	.30 (7.6)	.10 (2.5)	.36 (9.1)	.15 (3.8)
2S	.30 (7.6)	.12 (3.0)	.36 (9.1)	.09 (2.3)
2	.30 (7.6)	.12 (3.0)	.36 (9.1)	.15 (3.8)
2L	.30 (7.6)	.12 (3.0)	.33 (8.4)	.21 (5.3)

Figure 1. SILASTIC® H. P. Hammer toe implant, Dow Corning Wright (Reproduced by permission).



TYPICAL DIMENSIONS

Size	A	B	C	D	E
10	.138/3.5	.247/6.3	.442/11.2	.138/3.5	.171/4.3
20	.152/3.9	.347/8.8	.523/13.3	.138/3.5	.209/5.3
30	.166/4.2	.409/10.4	.523/13.3	.143/3.6	.223/5.7
40	.180/4.6	.409/10.4	.523/13.3	.152/3.9	.271/6.9

Size = Inches/Millimeters

Figure 2. Sutter Lesser Toe Proximal Interphalangeal Joint prosthesis (Sgarlato Design) (Reproduced by permission).

Sgarlato Hammer Toe Implant Prosthesis, Sgarlato Laboratories

This is the newest implant to be developed, and is also a double-stemmed device with a trapezoidal-shaped solid central portion and rectangular stems. Use of this implant has been limited because it is so new. However, the authors' experience indicates that the stems are too short to remain stable once they are placed into their respective medullary canals, and may predispose to dislocation (Fig. 4).

A visual comparison of the three implants is shown in Figure 5. These may be easily compared. Attention is directed to both the relative stem length and central body size.

Figure 5. Comparison of the three implants: (A) Sutter, (B) Dow Corning, (C) Sgarlato.

Technique

The procedure for digital arthroplasty with silicone prosthetic implant consists of resection of the head of the proximal phalanx of the second, third, fourth, and/or fifth toe, followed by insertion of the implant into the medullary canals of the intermediate phalanx and remaining proximal phalanx. Almost without exception, two semi-elliptical, longitudinal incisions are placed over the proximal interphalangeal joint (PIPJ), with the skin and enclosed lesion resected (Fig. 6). The purpose of the two curved incisions and removal of skin wedge is to narrow circumference of the toe and help prevent the swollen digit syndrome so often associated with hammer toe surgery.

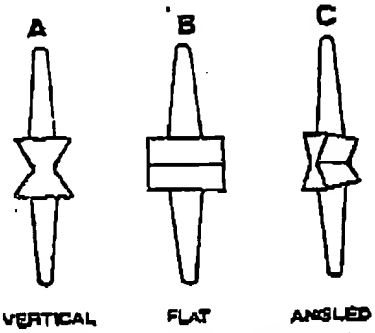
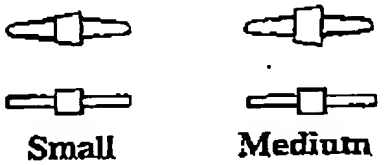


Figure 3. Line drawing of Sutter implant in three positions (A) vertical, (B) flat, and (C) angled.



SHIP IMPLANT

Figure 4. Sgarlato Hammertoe Implant Prosthesis (SHIP).

A linear incision is then placed in the dorsal tendinous structure on either its medial or lateral edge, that parallels the length of tendon from its distal attachment at the base of the distal phalanx, proximal to the middle of the shaft of the proximal phalanx (Fig. 7). The tendinous structure is carefully dissected either medially or laterally (depending on the initial incision), and the PIPJ is exposed. Care is taken not to detach the tendon either distally or proximally, nor to sever the tendon over the joint.

The purpose for this type of dissection is to provide a solid, nontraumatized section of tendon for coverage of the joint and implant. The entire tendinous structure is then retracted to expose the PIPJ (Fig. 8). The PIPJ is entered by severing the capsular ligaments and the head of the proximal phalanx is exposed. The bone is cut with an oscillating saw immediately proximal to the surgical neck of the phalanx (Fig. 9). More bone is removed than usual in the traditional arthroplasty without implant. The cut is generally made 6 to 9 mm. proximal to the most distal aspect of the head of the proximal phalanx. An oscillating saw is preferable to a bone cutting forceps because it will make a finer cut that is less likely to produce splintering or fracture, which may lead to hypertrophy of the remaining phalanx (Fig. 10).

The proximal phalanx is grasped with a phalangeal clamp, and the medullary canal is drilled or reamed to accept the proximal stem of the implant. This may be accomplished with a reamer, broach, or rotating burr. Care must be taken during this part of the procedure, especially with a drill or burr, not to penetrate the cortical wall of the proximal phalanx. The authors prefer a burr because it is quicker, and makes a round

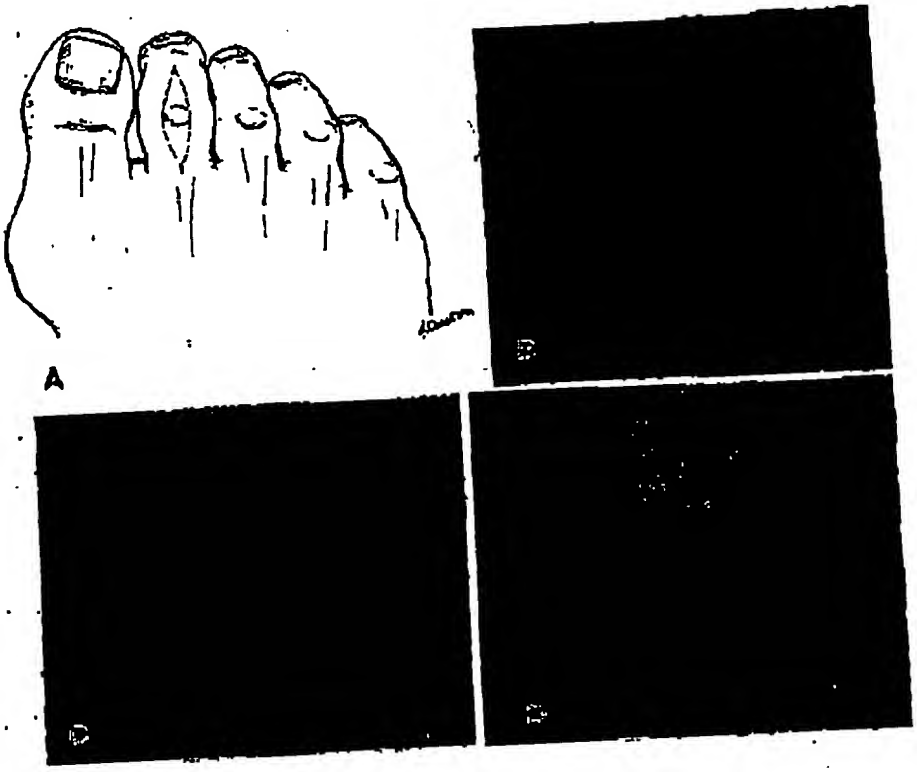


Figure 6. *A*, Two longitudinal semi-elliptical skin incisions; *B*, large lesion on the fifth digit over the proximal interphalangeal joint; *C*, two semi-elliptical incisions; *D*, skin wedge and lesion being removed.

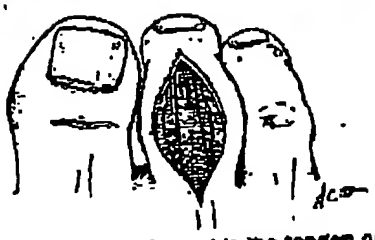


Figure 7. Linear incision along side the tendon apparatus.

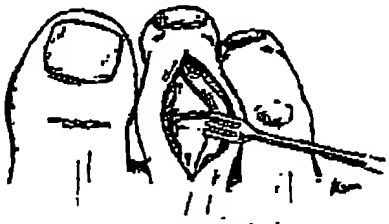


Figure 8. Tendon apparatus retracted.

hole that allows for easier rotation of the implant (Fig. 11). A corresponding hole is then placed in the base of the intermediate phalanx. It is not necessary to resect any portion of the intermediate phalanx. Frequently,

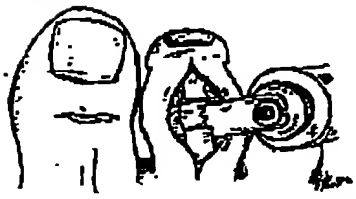


Figure 9. Proximal phalanx is cut with an oscillating saw 6 to 9 mm. from the distal end of the head.

additional soft tissue dissection is necessary to allow for adequate visualization of the base of the intermediate phalanx.

The area is irrigated and stems of the desired implant are placed in the appropriate bones (Fig. 12). A common misconception at this stage of the procedure is that the shaft of the proximal and base of the intermediate phalanges must be in contact with the central portion of the implant. There should be a 2 to 3 mm. space between the implant and each bone. If this space is not present, an adequate amount of bone has not been resected from the proximal phalanx, and lesion recurrence may be more likely (Fig. 13).

Consideration must be given to the attitude of the implant once it is in place. There are certain instances

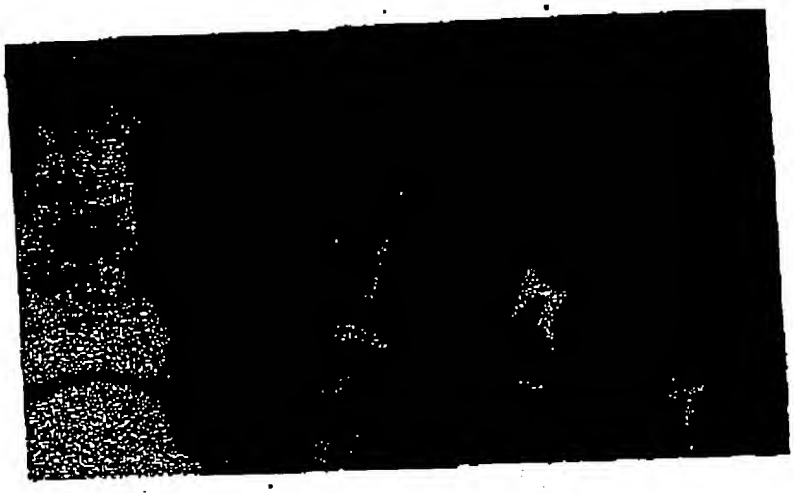


Figure 10. Note bony hypertrophy of the cut end of the proximal phalanges following arthroplasty.

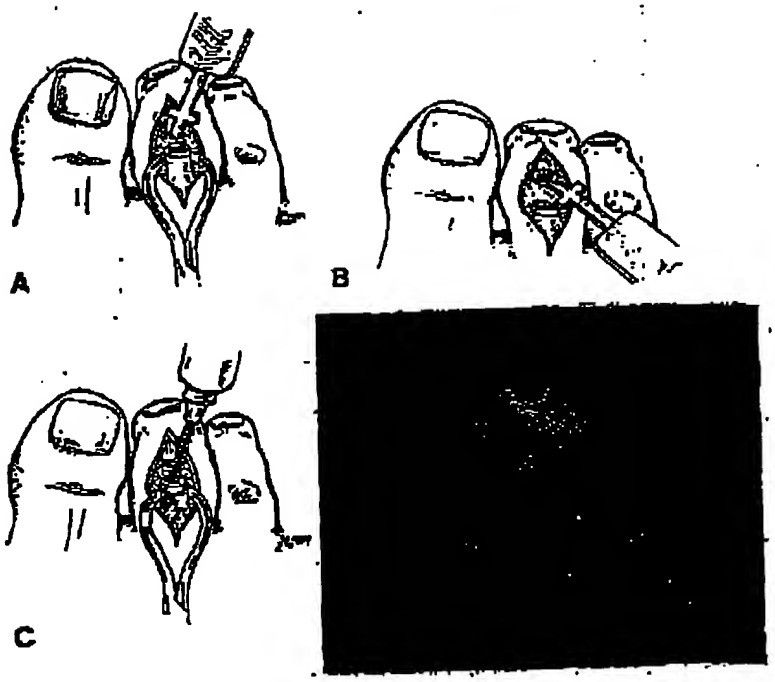


Figure 11. *A*, Medullary canal of proximal phalanx reamed; *B*, intermediate phalanx reamed; *C*, rotating burr accidentally penetrating shaft of the proximal phalanx; *D*, medullary canal of the proximal phalanx prepared for implant.

When it is appropriate to rotate the device between 10 and 90 degrees from the flat or horizontal position to a vertical one (Fig. 3). This rotation is possible with only the Sutter and Sgarlato devices, and is addressed in great detail later in the paper. The tendinous apparatus is repaired with 5-0 absorbable suture, and skin is closed with 5-0 nylon interrupted suture. A small piece of Owens Dressing[5] is applied, and the toe is loosely wrapped with a small gauze that has been soaked in Betadine.[6] As this dries over the next 24 hr, a firm, compressive splint forms that prevents swelling. The dressing is reinforced with additional gauze, and the patient is usually fitted with a postoperative splint. Redressing is performed in 4 days. The Betadine splint dressing is reapplied and continued through the first 2 postoperative weeks. This is followed by Gauzetex[7]

[5] Owens, American Cyanamid Co., Danbury, Connecticut 06810.

[6] Betadine Surgical Scrub—The Purdue Frederick Co., Norwalk, Connecticut 06856.

[7] Gauzetex, General Bandages, Inc., Morton Grove, Illinois 60053.

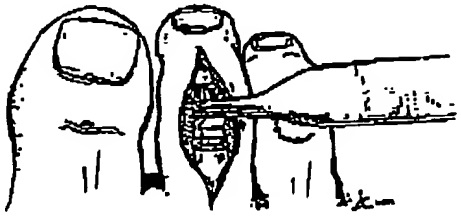


Figure 12. Implant placed into each bone.

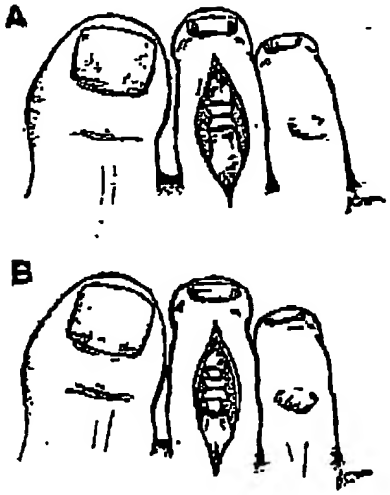


Figure 13. *A*, Central portion of the implant is flush with the proximal and intermediate phalanges (incorrect); *B*, 2- to 3-mm. space between the central portion of the implant and each bone.

wrapping for an additional 3 weeks. The patient is usually wearing a regular shoe by the end of the 2nd week.

The Fifth Toe

There exists widespread controversy over whether digital implant arthroplasty should be performed on the fifth toe. Most studies reviewed reported the procedure on all four lesser digits. However, there was a greater incidence of complications associated with the fifth digit. The authors found that by utilizing a Sutter device, with the advantage of a small central portion whose thickness is less than its width, the surgeon has the ability to insert this particular implant in the fifth digit in several different positions (angled or vertical), so as to avoid pressure from adjacent tissues or shoe gear (Fig. 14). Thus, postoperative swelling, irritation, and lesion recurrence, all common problems associated with fifth toe implant arthroplasty, can be greatly reduced.

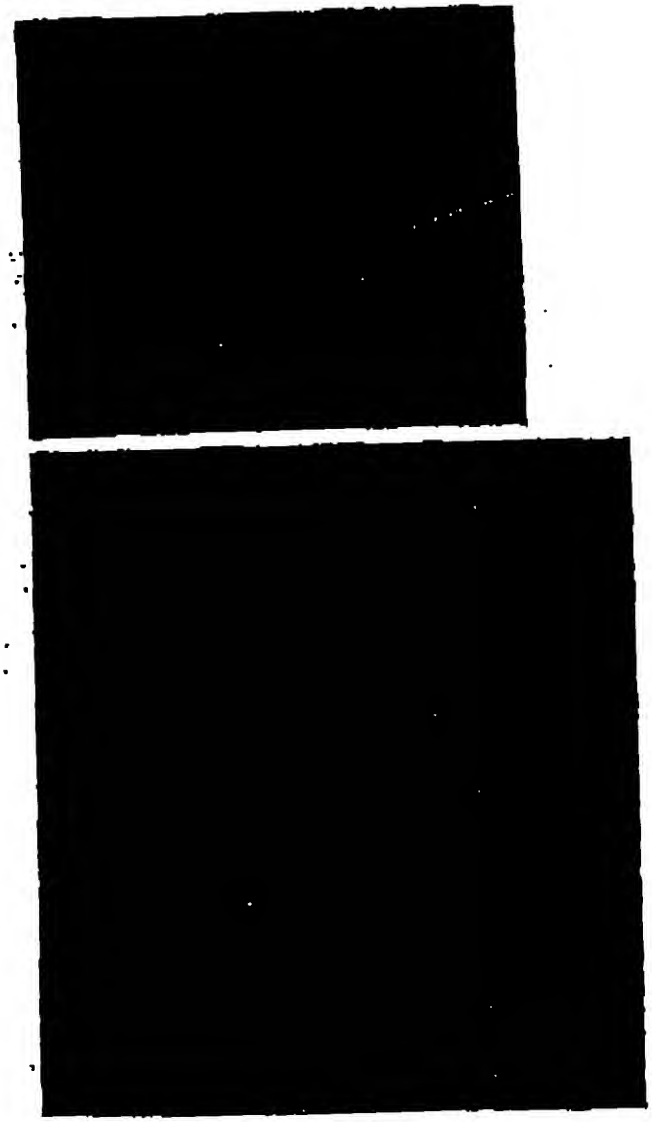


Figure 14. *A*, Note angulation of the central portion of the implant in relation to the toenail; *B*, x-ray of implant in vertical position.

Results

The following statistics are based on an 11-year study covering the use of digital implants. A total of 672 devices were placed into the lesser digits between 1979 and 1990. One hundred twenty-four were in the second

TABLE 1. The use of digital implants

Type of implant	Number implanted	Number removed	Percentage removed
Dow Corning	84	12	14.3
Sutter	585	2	0.003
Sgarlato (usage limited to only 6 months	3	0	0
Total	672	14	0.021

toe; fifty-four in the third digit; ninety-two in the fourth toe; and four hundred two in the fifth toe. Fourteen implants were removed (Table 1). The reasons for removal are described (Table 2). An in-depth discussion of the management and prevention of complications will be presented later. As shown by the statistics in these tables, the Sutter type implant produced far fewer complications and resulted in a much smaller percentage of removal than the Dow Corning model. The major reason for this is believed to be the difference in shape and size of the central portion of the implants. Experience with the Sgarlato device has been very limited, but these authors find its greatest drawbacks to be the short stem length and thickness of the central section.

Patient satisfaction with the digital implant procedure was rated according to three categories: very satisfied, satisfied, and dissatisfied. The degree of satisfaction was assessed no sooner than 12 months postoperatively. It was determined according to the factors cited in Table 3. An additional analysis of the long-term results of seven independent practitioners from various geographic regions is also provided (Table 4). These statistics were compiled by the author from an informal questionnaire that was completed by these surgeons.

The total number of implants inserted was 2670. Five hundred thirty-seven were Dow Corning, 1974 were Sutter, and 159 were Sgarlato design. Of the overall total, 42 were removed. This is consistent with the authors' findings. The most common reason for removal was swelling or discomfort of the toe, followed by lesion recurrence, and a very small number of infections. These results, although strictly anecdotal, corroborate the authors' results discussed previously.

TABLE 2. Reasons for removal

	Total	Dow Corning	Sutter	Sgarlato (usage limited to only 6 months)
Discomfort/swelling	6	5	1	
Lesion recurrence	5	5		
Infection	2	1	1	
Material failure	1	1		
Rejection	0			
Total	14	12	2	

TABLE 3. Patient satisfaction

	Very Satisfied	Satisfied	Dissatisfied
Types of shoes worn comfortably	All	Most	Few
Elimination of lesion	Complete	Partial	Recurrent
Swelling of digit	None	Slight	Large
Activity level without pain	Full	Moderate	Limited

TABLE 4. Results

Very satisfied	82%
Satisfied	10%
Dissatisfied	8%

TABLE 5. Complications associated with digital implant arthroplasty (in order of frequency)

Discomfort or prolonged swelling of the digit
Lesion recurrence
Infection
Biomaterial failure
Rejection
Bone damage

Potential Complications-Management and Prevention

Complications from digital implant arthroplasty are rare (0.021%). However, it is appropriate to describe potential complications, their management and prevention. This is based on the senior authors' experience over a 10-year period, as well as the input of several surgeons who have had extensive experience with this technique. Listed in order of frequency, the complications most often encountered are noted in Table 5.

Discomfort or Prolonged Swelling of the Digit

This the most common postoperative problem associated with digital implant arthroplasty, and is best prevented on the operating table at the time of skin incision. In nearly all of the operated toes, two semi-elliptical incisions are placed to encompass the lesion, and the skin and lesion between these two incisions are excised. This accomplishes two things: first, the lesion is removed, and second, the circumference of the digit is reduced, thereby providing compression and protection from the postoperative "fat toe" syndrome.

At the conclusion of the procedure, the operated toe is dressed with moderate compression using a folded 2 × 2 gauze soaked in Betadine that, upon drying, creates a compressive mini cast on the digit. This procedure is repeated at the first two redressings for a period of 2 weeks. The compression continues with an adhesive gauze wrap such as Gauzetex for an additional 3 to 6 weeks. If swelling and discomfort persists, it may be necessary to remove the implant. This is never performed sooner than 6 weeks postoperatively, unless infection is a factor. Once the implant has been in place at least 6 weeks, the full benefit of the device has been achieved. Fibrous tissue that will stabilize the toe and serve to maintain digital length (the two major goals of implant surgery) is now present and relatively mature. The author has found no basic clinical difference in the digits from which implants were removed after at least 6 weeks, and those that have implants in place permanently.

Lesion Recurrence

Recurrence of the lesion can be troublesome and disconcerting for the patient. With digital implant arthroplasty, the most common cause for lesion recurrence has been found to be selection of the inappropriate implant (Fig. 15), and improper placement or prominence of the central body of the prosthesis. Table 2 demonstrates that out of five implants removed because of recurrence, all were Dow Corning. This is believed to be because of the relatively large, cylindrical shape of the central portion (Fig. 16). All of the recurrences were either fifth toe or fourth interspace lesions. The authors have devised several ways to prevent this with use of the Suner implant. Because the central portion of this particular device is thinner from top to bottom than side to side (Figs. 2, 3), the surgeon has an option to place the implant into the toe in a variety of positions. For example, in the second, third, and fourth

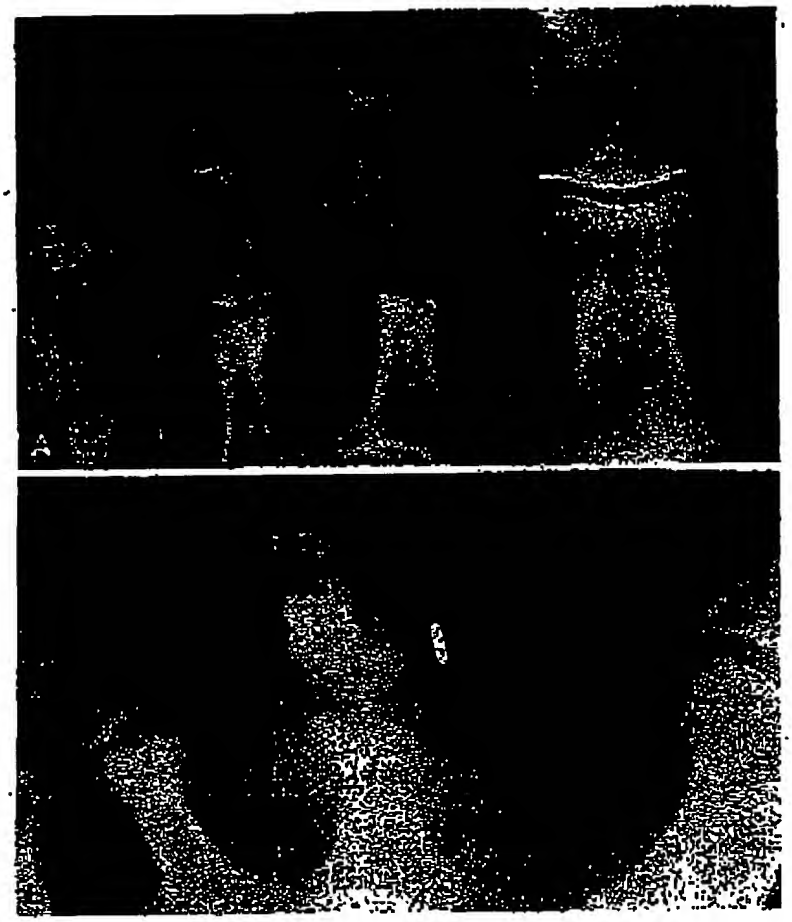


Figure 15. *A*, Finger joint prosthesis used in toe. Note medial and lateral protrusion; *B*, protrusion on medial side of finger joint implant.

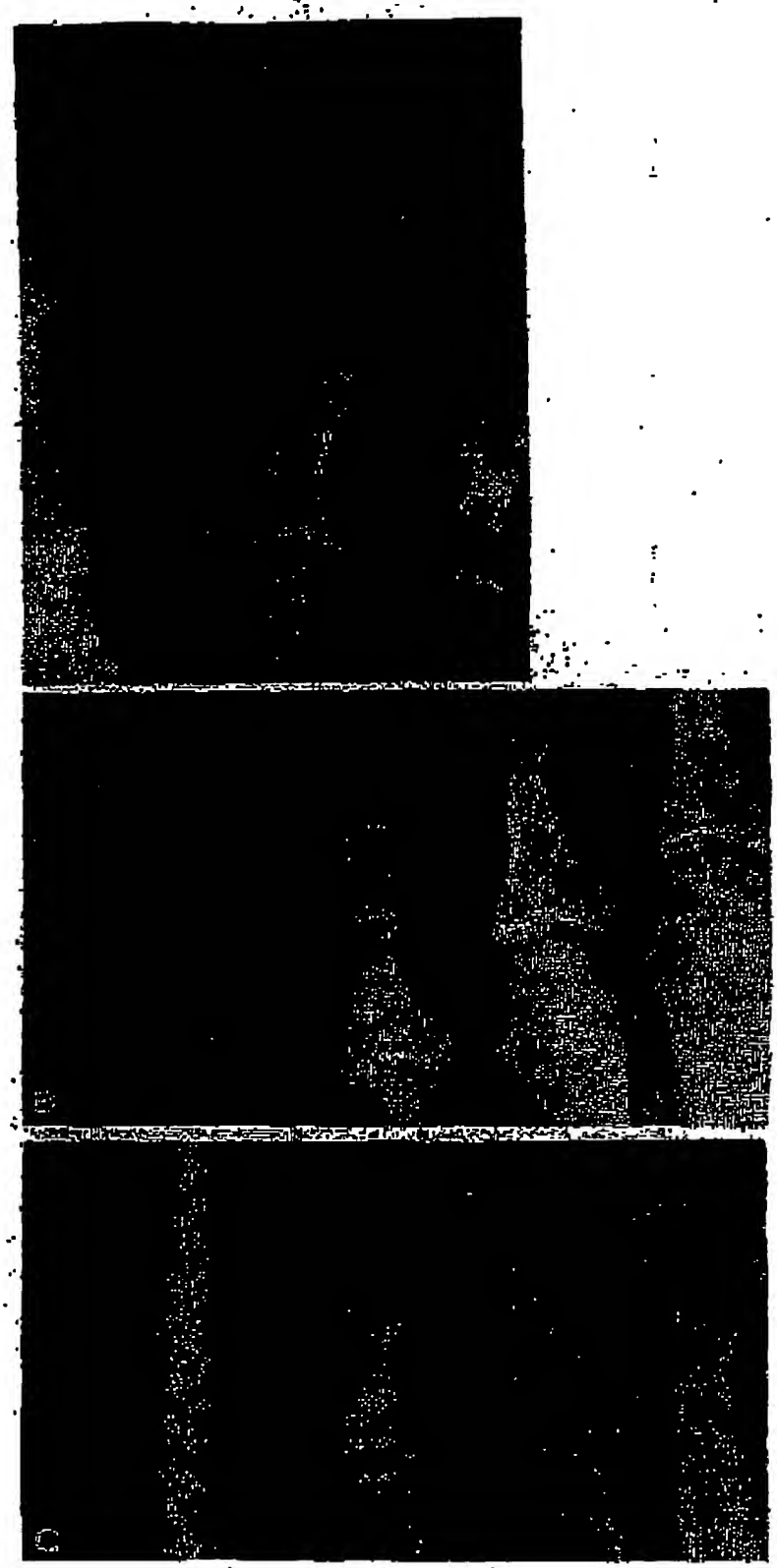


Figure 16. *A*, X-ray of Dow Corning implant in second toe. Note compression and bulging of implant. *B*, x-ray of Dow Corning implant in fifth toe. Note excessive size of central portion. *C*, another view of Dow Corning implant in fifth toe.

toe, the device is usually placed in a flat or horizontal attitude (Fig. 17). In cases of a dorsolateral lesion on the fifth toe, the device may be placed at a 45 degree angle, so the flat surface of the implant is next to the area of greatest pressure (Fig. 14A). Of particular importance is the placement of the implant when confronted with a fourth interspace lesion. In this instance, the device is situated at a 90 degree angle or vertical (Fig. 14B). The ability to place the Sutter implant in various positions has resulted in a significant reduction in the incidence of lesion recurrence.

Infection

Infection of the implant site requires immediate response on the part of the surgeon. Culture and sensitivity, Gram stain, laboratory studies, and clinical signs and symptoms all must be carefully considered. If the appropriate antibiotic does not produce rapid resolution of the infection, removal of the implant is required (29). The authors recommend waiting no more than 5 to 7 days following initiation of therapy to remove the implant if no obvious progress is being made.

The practitioner must be aware of the appropriate length and dosage of antibiotic administration to achieve complete resolution of the problem. As a means of prevention of infection, appropriate intraoperative, prophylactic intravenous antibiotic therapy is routinely used when digital implant arthroplasty is performed. Additionally, patients at risk for infection are not generally subjected to this procedure.

Biomaterial Failure

Only one case of failure of the implant was noted. This presented as a breakage of the stems on a Dow Corning device. It is hypothesized that the low rate of biomaterial fatigue and subsequent failure is due to the

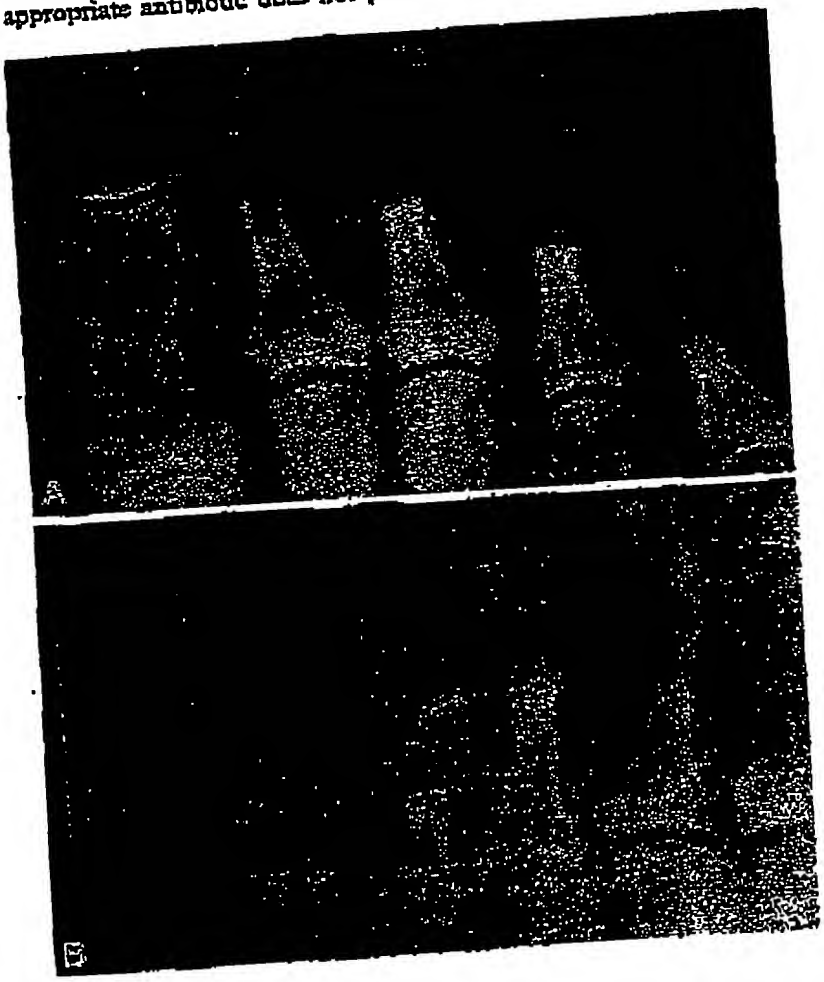


Figure 17. A, X-ray of implants in four lesser toes. Note flat position of the implants in the second, third, and fourth toes; B, note flat or horizontal position of implant in the fourth toe.

fact that little to no stress is placed on the device during ambulation (Fig. 18).

Reactive Synovitis

Synovitis, or formation of bone cysts around the implant, have been reported. The authors have observed this in and around the first metatarsophalangeal joint. However, this was not found to be a significant factor in digital implant surgery. Synovitis with foreign-body giant cell response to particulate silicone, appears a potential complication of SILASTIC® implant arthroplasties. The exact mechanism of this reactive synovitis is unknown. Studies indicate that the silicone elastomer in particulate form has a greater tendency to trigger inflammatory response than do larger volume implants (30). Decreased mechanical stress placed on digital implants, as opposed to first metatarsophalangeal joint prostheses, induce less abrasion and erosion, which may account for the reduced incidence of silicone synovitis in the toes.

Bone Damage

Injury to bone can occur when preparing the medullary canal of the proximal or intermediate phalanx to accept the stems of the implant. The authors suggest use of a reamer or broach, specifically designed for this purpose, but also have no difficulty drilling the canals with a rotating burr so long as caution is exercised. Selecting the appropriate sized burr, obtaining adequate visualization of the bony surfaces, and directing the burr at a proper angle are all important considerations, if a rotating burr is utilized. A phalangeal clamp is extremely beneficial in this procedure. The authors also recommend cutting the neck of the proximal phalanx with an oscillating saw, to avoid possible fracture of the

Figure 18. Implant removed because of material failure. Prosthetic stems have fractured.

TABLE 6. Contraindications

Medically compromised patient
Poor bone stock
Previous infection
Unduly small proximal phalanx
Allergic history to silicone
Inadequate circulatory status
Poor skin integrity

shaft, and spiculization that may promote osseous regrowth over a period of time (Fig. 10).

Contraindications

There exist few contraindications to digital implant arthroplasty. However, the surgeon must be cognizant of potential risks and ramifications of performing this operation. Common contraindications are listed in Table 6.

Conclusion

Digital implant arthroplasty has proven to be an excellent procedure for correction of hammer toe deformity with a proximal interphalangeal joint lesion of the second, third, fourth, or fifth digit. Additionally, fourth interspace lesions respond well to this procedure when a precipitating factor is the head of the fifth proximal phalanx. The authors have found the procedure to be most successful utilizing the Sutter implant. This success is attributable to the size and shape of the central portion, and the stem length of the implant. The Scarlato design has been in use for approximately 1 year, so experience with it is limited. However, the short stem length does present a potential problem with dislocation. The Dow Corning implant is no longer used by the authors because of the excessive size of the central portion of the device.

Compared with other techniques (Kirschner-wire fixation and fusion) utilized to reduce the common complications of arthroplasty, such as flacidity and shortening of the toe, silicone implantation has proven to be far superior and is recommended in the appropriate preoperative circumstances (Table 6).

Acknowledgment

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